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**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

UNITED STATES OF AMERICA *et al. ex rel.*
MARC D. BAKER,

Plaintiffs,

v.

WALGREENS, INC.,

Defendant.

12 Civ. 0300 (JPO)

UNITED STATES OF AMERICA,

Plaintiff-Intervenor,

v.

WALGREEN CO.,

Defendant.

12 Civ. 0300 (JPO)

Plaintiff United States of America (“United States” or “Government”), by its attorney, Preet Bharara, United States Attorney for the Southern District of New York, brings this action against Walgreen Co. (“Walgreens”), alleging upon information and belief as follows:

PRELIMINARY STATEMENT

1. This is a civil action brought by the United States against Walgreens under the False Claims Act, 31 U.S.C. §§ 3729 *et seq.* (“FCA”), and the common law to recover damages sustained by, and civil penalties owed to, the United States based on Walgreens’ violation of the Anti-Kickback Statute (“AKS”), 42 U.S.C. § 1320a-7b, in connection with its enrollment of beneficiaries of government healthcare programs — specifically, beneficiaries of the Medicare, Medicaid and TRICARE programs (“government beneficiaries”) — in its Prescription Savings Club program (“PSC program”). As set forth more fully below, from January 1, 2007, through December 31, 2010 (“Covered Period”), Walgreens violated the AKS and the FCA by enrolling hundreds of thousands of government beneficiaries in the PSC program — and providing them with discounts on prescription medications and other monetary benefits pursuant to the PSC program — in order to induce them to self-refer all of their prescription drug purchases to Walgreens’ pharmacies.

2. Under the AKS, it is unlawful for a pharmacy like Walgreens to knowingly and willfully offer or pay remuneration to a government beneficiary in order to induce such person to purchase a drug from the pharmacy for which payment may be made in whole or in part by a government healthcare program. Throughout the Covered Period, the benefits that Walgreens provided to PSC program members (which are described below) qualified as remuneration.

3. Walgreens launched the PSC program in 2007. Throughout the Covered Period, the PSC program provided PSC program members with discounts on thousands of brand-name and generic drugs, as well as a 10% rebate on all Walgreens’ branded products, including household products, baby-care products, most grocery items, and non-prescription medications.

Walgreens intended these lower drug prices and other benefits to be an inducement to its existing and potential customers to cause them to patronize Walgreens for all of their pharmacy needs.

Walgreens feared that if it did not offer these benefits to its customers, many of them would take their pharmacy business to one of Walgreens' competitors.

4. Given the nature of the PSC program (*i.e.*, a discount program through which Walgreens intended to induce its existing and potential customers to self-refer all of their pharmacy business to Walgreens), Walgreens recognized that allowing government beneficiaries to participate in the PSC program would violate the AKS. Specifically, Walgreens recognized that the features of the PSC program that made it attractive to its customers generally would act as an unlawful inducement if made available to government beneficiaries, as it would prompt them to patronize Walgreens for all of their prescription medication needs, including those paid for in whole or in part by government healthcare programs. Accordingly, throughout the Covered Period, Walgreens consistently maintained in its published materials regarding the PSC program that government beneficiaries were ineligible to participate in the program.

5. Notwithstanding Walgreens' understanding that allowing government beneficiaries to participate in the PSC program would violate the AKS — as well as its published materials stating that government beneficiaries were excluded from the program — during the Covered Period, Walgreens consistently marketed the PSC program to government beneficiaries. For example, when a customer who was not a PSC program member picked up a prescription at a Walgreens' pharmacy, Walgreens provided the customer with a leaflet identifying the amount the customer would purportedly save on the prescription if he or she was a PSC program member. Walgreens provided these leaflets to all types of customers, including government beneficiaries.

6. Moreover, throughout the Covered Period, Walgreens incentivized its employees to enroll customers in the PSC program, regardless of whether they were government beneficiaries. For example, from May 2008 through August 2010, Walgreens paid its employees from \$1 to \$5 for each customer they enrolled in the PSC program. In making these incentive payments, Walgreens did not check whether any of the customers who had been enrolled were government beneficiaries.

7. As a result of the above-described and other conduct, during the Covered Period, Walgreens enrolled hundreds of thousands of government beneficiaries in the PSC program. Moreover, during the Covered Period, Walgreens knew that it was enrolling substantial numbers of government beneficiaries in the PSC program. For example, in October 2007, Walgreens conducted an analysis of its PSC program members and found that approximately 13,000 of them were government beneficiaries. At that time, Walgreens removed those individuals from the PSC program, but it subsequently allowed many of those very same government beneficiaries to re-enroll in the program.

8. In addition, during the Covered Period — including after October 2007 — employees in Walgreens' pharmacies nationwide made notations in Walgreens' internal customer database reflecting that tens of thousands of government beneficiaries were enrolled in and purchasing prescription drugs using the PSC program.

9. Furthermore, throughout the Covered Period, Walgreens maintained data reflecting each prescription filled by each of its customers. A review of this data would have revealed that, during the Covered Period, there were hundreds of thousands of government beneficiaries enrolled in the PSC program. In fact, towards the end of the Covered Period, in August 2010, Walgreens conducted an analysis of PSC program members in one particular state,

and that analysis reflected that about half of the PSC program members in that state in 2009 and 2010 were government beneficiaries. Walgreens, however, failed to take action in response to this and other evidence from after October 2007 of government beneficiary participation in the PSC program.

10. The discounts and other benefits that Walgreens provided to government beneficiaries pursuant to the PSC program constituted unlawful kickbacks under the AKS, as they were an inducement to the government beneficiaries to patronize Walgreens for all of their prescription drug needs, including to fill prescriptions that were paid for in whole or in part by government healthcare programs.

11. Walgreens not only provided the above-referenced kickbacks to government beneficiaries — which induced the beneficiaries to fill prescriptions at Walgreens' pharmacies using their government healthcare programs — but it also sought reimbursement from the government healthcare programs for those kickback-tainted prescriptions. As a result of this conduct, Walgreens knowingly submitted and caused to be submitted false claims for payment to federal healthcare programs (specifically, the Medicare, Medicaid and TRICARE programs), and it is liable under the FCA and the common law for damages and penalties for those false claims, as discussed in detail below.

JURISDICTION AND VENUE

12. This Court has jurisdiction over the claims brought under the False Claims Act pursuant to 31 U.S.C. § 3730(a) and 28 U.S.C. §§ 1331 and 1345, and over the remaining claims pursuant to 28 U.S.C. § 1345.

13. Venue lies in this District pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. §§ 1391(b) and 1391(c), because Walgreens does business in this district and some of the false or fraudulent acts occurred in this district.

PARTIES

14. Plaintiff is the United States of America suing on its own behalf and on behalf of the United States Department of Health and Human Services (“HHS”), and its component agency, the Centers for Medicare and Medicaid Services (“CMS”) (formerly known as the Health Care Financing Administration), which administers the Medicare program and is responsible for overseeing the Medicaid program. Plaintiff is also suing on behalf of the Department of Defense, which administers the TRICARE/CHAMPUS program (TRICARE”).

15. In January 2012, Marc D. Baker (“Relator”) filed this action under the *qui tam* provisions of the FCA, alleging, *inter alia*, that Walgreens had violated the AKS and FCA in connection with its enrollment of government beneficiaries in the PSC program. Relator filed an amended complaint in December 2013. Relator worked for Walgreens as a pharmacy manager in Florida from April 2001 until December 2011.

16. Defendant Walgreens is a nationwide retail pharmacy chain, which during the Covered Period, owned and operated thousands of retail pharmacies located across the United States, including in the Southern District of New York. During the Covered Period, Walgreens enrolled government beneficiaries located in the Southern District of New York in the PSC program.

FACTUAL ALLEGATIONS

I. The Anti-Kickback Statute and the False Claims Act

17. The FCA establishes liability to the United States for an individual who, or entity that, “knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval,” 31 § 3729(a)(1)(A); or “knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim,” *id.* § 3729(a)(1)(B).¹ “Knowingly” is defined to include actual knowledge, reckless disregard and deliberate indifference.

Id. § 3729(b)(1). No proof of specific intent to defraud is required. *Id.*

18. The AKS makes it illegal for individuals or entities to knowingly and willfully “offer[] or pay[] remuneration (including any kickback, bribe, or rebate) . . . to any person to induce such person . . . to purchase, . . . order, . . . or recommend purchasing . . . or ordering any good . . . or item for which payment may be made in whole or in part under a Federal health care program.” 42 U.S.C. § 1320a-7b(b)(2). Under the circumstances of this case, the discounts and other benefits that Walgreens provided to government beneficiaries pursuant to the PSC program are examples of such illegal remuneration. Violation of the AKS is a felony punishable by fines

¹ In May 2009, the False Claims Act was amended pursuant to Public Law 111-21, the Fraud Enforcement and Recovery Act of 2009 (“FERA”). Section 3729(a)(1)(B) was formerly Section 3729(a)(2), and is applicable to Walgreens’ conduct for the entire time period alleged in this Complaint by virtue of Section 4(f) of FERA. Section 3279(a)(1)(A), formerly Section 3729(a)(1) of the FCA prior to FERA, and as amended in 1986, applies to conduct on or after May 20, 2009. Section 3729(a)(1) of the pre-FERA FCA provides, in pertinent part, that:

- (a) Any person who (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval . . .

* * *

is liable to the United States Government for a civil penalty of not less than \$5,000 and not more than \$10,000, plus 3 times the amount of damages which the Government sustains because of the act of that person

and imprisonment and can also result in exclusion from participation in federal healthcare programs. 42 U.S.C. § 1320a-7b(b)(2); 42 U.S.C. § 1320a-7(b)(7).

19. Compliance with the AKS, 42 U.S.C. § 1320a-7b(b), is a condition of payment under federal healthcare programs.

20. In connection with its payment of kickbacks to government beneficiaries inducing them to self-refer their prescriptions to Walgreens' pharmacies (including prescriptions that were paid for in whole or in part by government healthcare programs), Walgreens both submitted and caused the submission of false claims to federal healthcare programs.

21. Pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996, 28 U.S.C. § 2461 (notes), and 64 Fed. Reg. 47099, 47103 (1999), the FCA civil penalties are \$5,500 to \$11,000 for violations, such as those alleged here, occurring on or after September 29, 1999.

II. The Federal Healthcare Programs

22. When a physician prescribes a pharmaceutical product to a patient, the patient is provided with a prescription that is filled at a pharmacy. Where the patient is a government beneficiary, the pharmacy then submits the claim for payment to the relevant federal healthcare program for reimbursement.

23. **Medicare.** Medicare is a federal program that provides federally subsidized health insurance primarily for persons who are 65 or older or disabled. *See* 42 U.S.C. §§ 1395 *et seq.* ("Medicare Program"). Part D of the Medicare Program was enacted as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, to provide prescription drug benefits for Medicare beneficiaries. Medicare Part D became effective January 1, 2006. All persons enrolled in Medicare Part A and/or Medicare Part B are

eligible to enroll in a prescription drug plan under Part D. HHS, through its component agency, CMS, contracts with private companies (or “Part D sponsors”) to administer prescription drug plans. Such companies are regulated and subsidized by CMS pursuant to one-year, annually renewable contracts. Part D sponsors enter into subcontracts with many pharmacies to provide drugs to the Medicare Part D beneficiaries enrolled in their plans.

24. Generally, after a physician writes a prescription for a patient who is a Medicare beneficiary, that patient can take the prescription to a pharmacy to be filled. When the pharmacy dispenses drugs to the Medicare beneficiary, the pharmacy submits a claim electronically to the beneficiary’s Part D sponsor (sometimes through the sponsor’s pharmacy benefit manager, or “PBM”). The pharmacy receives reimbursement from the sponsor (or PBM) for the portion of the drug cost not paid for by the beneficiary. The Part D sponsor is then required to submit to CMS an electronic notification of the drug dispensing event, called the Prescription Drug Event (“PDE”), which contains data regarding the prescription claim, including the pharmacy that dispensed the drug, the prescriber of the drug, the quantity dispensed, the amount that was paid to the pharmacy, and whether the drug is covered under the Medicare Part D benefit.

25. Payments by CMS to a Part D Plan sponsor are conditioned on the provision of information to CMS that is necessary for CMS to administer the Part D program and make payments to the Part D Plan sponsor for qualified drug coverage. 42 C.F.R. § 423.322. CMS’s instructions for the submission of Part D prescription PDE claims data state that “information . . . necessary to carry out this subpart” includes the data elements of a PDE. PDE records are an integral part of the process that enables CMS to administer the Part D benefit. Each PDE that is submitted to CMS is a summary record that documents the final adjudication of a dispensing

event based upon claims received from pharmacies and serves as the request for payment for each individual prescription submitted to Medicare under the Part D program.

26. CMS gives each Part D sponsor advance monthly payments consisting of the Part D sponsor plan's direct subsidy per enrollee (which is based on a standardized bid made by the Part D sponsor), estimated reinsurance subsidies for catastrophic coverage, and estimated low-income subsidies. 42 C.F.R. §§ 423.315, 423.329. At the end of the payment year, CMS reconciles the advance payments paid to each Part D sponsor with the actual costs the sponsor has incurred. In this reconciliation process, CMS uses the PDE claims data it has received from the Part D sponsor during the prior payment year to calculate the costs the Part D sponsor has actually incurred for prescriptions filled by Medicare beneficiaries under Part D. If CMS underpaid the sponsor for low-income subsidies or reinsurance costs, it will make up the difference. If CMS overpaid the sponsor for low-income subsidies or reinsurance costs, it will recoup the overpayment from the sponsor. After CMS reconciles a plan's low-income subsidy and reinsurance costs, it then determines risk-sharing amounts owed by the plan to CMS or by CMS to the plan related to the plan's direct subsidy bid. Risk-sharing amounts involve calculations based on whether and to what degree a plan's allowable costs exceeded or fell below a target amount for the plan by certain threshold percentages. 42 C.F.R. § 423.336.

27. The payments made by CMS to the Part D sponsor come from the Medicare Prescription Drug Account, an account within the Federal Supplementary Medical Insurance Trust Fund. 42 C.F.R. § 423.315(a).

28. In order to receive Part D funds from CMS, Part D sponsors, as well as their authorized agents, employees, contractors, and subcontractors (including pharmacies), are required to comply with all applicable federal laws, regulations, and CMS instructions.

29. By statute, all contracts between a Part D sponsor and HHS must include a provision whereby the sponsor agrees to comply with the applicable requirements and standards of the Part D program as well as the terms and conditions of payment governing the Part D program. 42 U.S.C. § 1395w-112.

30. Medicare Part D sponsors must also certify in their contracts with CMS that they agree to comply with all federal laws and regulations designed to prevent fraud, waste, and abuse, including the FCA and AKS. 42 C.F.R. § 423.505(h)(1).

31. In accordance with these express statutory and regulatory requirements, all contracts entered into between CMS and Part D sponsors from 2006 through the present include a provision in which the sponsor “agrees to comply with . . . federal laws and regulations designed to prevent . . . fraud, waste, and abuse, including, but not limited to, applicable provisions of Federal criminal law, the False Claims Act (31 U.S.C. §§ 3729 *et seq.*), and the anti-kickback statute (§ 1127B(b) of the Act).”

32. CMS regulations further require that all subcontracts between Part D sponsors and downstream entities — such as pharmacies like Walgreens and PBMs — contain language obligating the pharmacies and PBMs to comply with all applicable federal laws, regulations, and CMS instructions, which include the AKS. 42 C.F.R. § 423.505(i)(4)(iv).

33. **Medicaid.** Medicaid is a joint federal-state program created in 1965 that provides healthcare benefits for certain groups, primarily the poor and disabled. Each state administers a state Medicaid program. The federal Medicaid statute requires each participating state to implement a plan containing certain specified minimum criteria for coverage and payment of claims. 42 U.S.C. §§ 1396, 1396a(a)(13), 1396a(a)(30)(A). While drug coverage is an optional benefit, the Medicaid programs of all states provide reimbursement for prescription drugs.

34. The federal portion of each state's Medicaid payments, known as the Federal Medical Assistance Percentage ("FMAP"), is based on the state's per capita income compared to the national average. 42 U.S.C. § 1396d(b). Among the states, the FMAP is at least 50 percent and is as high as 83 percent. Federal funding under Medicaid is provided only when there is a corresponding state expenditure for a covered Medicaid service to a Medicaid recipient. The federal government pays to the state the statutorily established share of the "total amount expended . . . as medical assistance under the State plan." 42 U.S.C. § 1396b(a)(1).

35. The vast majority of states award contracts to private companies to evaluate and process claims for payment on behalf of Medicaid recipients. Typically, after processing the claims, these private companies then generate funding requests to the state Medicaid programs. Before the beginning of each calendar quarter, each state submits to CMS an estimate of its Medicaid federal funding needs for the quarter. CMS reviews and adjusts the quarterly estimate as necessary, and determines the amount of federal funding each state will be permitted to draw down as it incurs expenditures during the quarter. The state then draws down federal funding as actual provider claims, including claims from pharmacies seeking payment for drugs, are presented for payment. After the end of each quarter, the state then submits to CMS a final expenditure report, which provides the basis for adjustment to the quarterly federal funding amount (to reconcile the estimated expenditures to actual expenditures). 42 C.F.R. § 430.30.

36. Medicaid claims arising from illegal kickbacks are not authorized to be paid under relevant federal authority. Further, such claims are not payable under state regulatory regimes. For example, the New York regulatory regime provides that an "overpayment includes any amount not authorized to be paid under the medical assistance program, whether paid as the result of inaccurate or improper cost reporting, improper claiming, unacceptable practice, fraud,

abuse or mistake.” N.Y. Comp. Codes R. & Regs. Title 18 § 518.1(c). “Unacceptable practice” is defined to include “[b]ribes and kickbacks,” *id.* § 515.2(b)(5), and lists within this category both “soliciting or receiving,” *id.* § 515.2(b)(5)(ii), and “offering or paying,” *id.* § 515.2(b)(5)(iv), “either directly or indirectly any payment (including any kickback, bribe, referral fee, rebate or discount), whether in cash or in kind, in return for purchasing, leasing, ordering or recommending any medical care, services or supplies for which payment is claimed under the program,” *id.* § 515.2(b)(5)(ii), (iv). New York’s anti-kickback statute forbids kickbacks in similar terms. *See* N.Y. Soc. Serv. Law §§ 366–d, –f.

37. Providers who participate in the Medicaid program, including pharmacies, must sign enrollment agreements with their states that certify compliance with the state and federal Medicaid requirements, which include the AKS. Although there are variations among the states, the agreements typically require the prospective Medicaid providers to agree that they will comply with all state and federal laws and Medicaid regulations in billing the state Medicaid program for services or supplies (including prescription drugs) furnished.

38. Furthermore, in many states, Medicaid providers, including pharmacies, must affirmatively certify, as a condition of payment of the claims submitted for reimbursement by Medicaid, compliance with applicable federal and state laws and regulations, which include the AKS.

39. In New York, for example, providers, including pharmacies, must periodically sign a “Certification Statement for Provider Billing Medicaid,” in which the providers certify that claims submitted “to the State’s Medicaid fiscal agent, for services or supplies furnished,” “will be subject to the following certification. . . . I (or the entity) have furnished or caused to be

furnished the care, services, and supplies itemized and done so in accordance with applicable federal and state laws and regulations.”

40. **TRICARE.** TRICARE (formerly known as CHAMPUS) is part of the United States military’s healthcare system, designed to maintain the health of active duty service personnel, provide health care during military operations, and offer health care to non-active duty beneficiaries, including dependents of active duty personnel, and military retirees and their dependents. The military health system, which is administered by the Department of Defense (“DOD”), is composed of the direct care system, consisting of military hospitals and military clinics, and the benefit program, known as TRICARE. TRICARE is a triple-option benefit program designed to give beneficiaries a choice between health maintenance organizations, preferred provider organizations, and fee-for-service benefits.

41. TRICARE prescription drug benefits are provided through several different sources, including, as relevant here, TRICARE network and non-network retail pharmacies. TRICARE contracts with a PBM to administer the prescription drug benefits that are provided through network and non-network retail pharmacies.

42. When a TRICARE beneficiary brings a prescription to a TRICARE network retail pharmacy, the pharmacy submits an electronic claim to the PBM for that prescription event. The PBM sends an electronic response to the pharmacy that confirms the beneficiary’s TRICARE coverage, and, if the prescription claim is granted, informs the pharmacy of the calculated pharmacy reimbursement amount and the co-pay (if applicable) to be collected from the beneficiary. The pharmacy then collects the co-pay amount (if any) from the beneficiary and dispenses the medication. After a 10-day hold to ensure the prescription was picked up and not returned to the shelf by the pharmacy, the PBM sends a TRICARE Encounter Data (“TED”)

record electronically to TRICARE. The TED record includes information regarding the prescription event, including the reimbursement amount to be paid to the dispensing pharmacy. TRICARE then authorizes the PBM to make payment to the pharmacy for the amount remaining (after co-pay) on the claim. The PBM sends the payment to the pharmacy. After the payment is made by the PBM's bank, the PBM's bank requests reimbursement from the Federal Reserve Bank ("FRB"). The FRB then transfers funds to the PBM's bank account.

43. If the prescription is filled at a non-network retail pharmacy, the beneficiary must pay the full price of the prescription to the pharmacy and file a claim for reimbursement on DD Form 2642, TRICARE/DoD.CHAMPUS Medical Claim – Patient's Request for Medical Payment ("Form 2642"). The Form 2642 is mailed to the PBM. As in the case of reimbursements to TRICARE network retail pharmacies, a TED record is created by the PBM and sent to TRICARE. TRICARE then authorizes payment to the TRICARE beneficiary. Upon receiving that authorization, the PBM issues a check to the beneficiary, which is drawn on the PBM's bank account. TRICARE then reimburses the PBM in the same manner as it does under the network retail pharmacy scenario, such that funds are transferred from the FRB to the PBM's bank account.

44. Any providers providing services to TRICARE beneficiaries, including network and non-network retail pharmacies, are required to comply with TRICARE's program requirements, including its anti-abuse provisions. 32 C.F.R. § 199.9(a)(4). TRICARE regulations provide that claims submitted in violation of TRICARE's anti-abuse provisions are subject to denial. *Id.* § 199.9(b). Kickback arrangements are included within the definition of abusive situations that warrant the denial of claims. *Id.* §§ 199.2(b), 199.9(c)(12).

III. Walgreens Prescription Savings Club Program

45. Walgreens launched the PSC program in 2007.

46. Throughout the Covered Period, customers who enrolled in the PSC program were eligible to receive substantial discounts on thousands of generic and brand-name prescription medications.

47. PSC members were also eligible to receive other monetary benefits, including a 10% rebate on purchases of Walgreens' branded products, such as household products, baby care products, most grocery items, and non-prescription medications. When a PSC member made an eligible purchase and presented his or her PSC membership card at the time of purchase, 10% of the pre-tax purchase price of the item was credited to the PSC member's PSC card. The earned credits were then applied to the next eligible purchase the PSC member made.

48. Upon enrolling in the PSC program, a customer received his or her PSC membership card, which Walgreens referred to as the "WCard."

IV. Walgreens Understood that It Was a Violation of the AKS to Allow Government Beneficiaries to Participate in the PSC Program

49. Walgreens designed the PSC program to be attractive to, among others, current or prospective customers whose prescription drug insurance coverage was insufficient for some or all of their prescription drug needs. The PSC program offered such customers — which included government beneficiaries — the opportunity to obtain discounts on their prescription drugs where the discounted prices of the drugs under the PSC program were cheaper than the amounts the customers would have paid for the drugs under their existing healthcare programs.

50. As set forth above, the PSC program also offered such customers rebates on a wide variety of retail items sold at Walgreens' pharmacies, such as household products, baby-care products, most grocery items, and non-prescription medications.

51. Walgreens intended the PSC program discounts and rebates — including on prescription and non-prescription medications, as well as on consumer and household items — to serve as an inducement to its customers to prompt them to patronize Walgreens for all of their pharmacy needs. Walgreens feared that if it did not offer such discounts and rebates to its customers, many of them would take their pharmacy business to one of Walgreens' competitors.

52. However, Walgreens recognized that the monetary benefits offered through the PSC program that were intended to be attractive to under-insured customers generally would be equally attractive to government beneficiaries. Walgreens also recognized that if it made the PSC program discounts and rebates available to government beneficiaries, those discounts and rebates would be an inducement to such beneficiaries to obtain all of their prescription medications at Walgreens' pharmacies, including those paid for in whole or in part by government healthcare programs, which would constitute a violation of the AKS.

53. As a result, throughout the Covered Period, Walgreens consistently maintained in its published materials regarding the PSC program that government beneficiaries were not eligible to participate in the program.

54. Notably, early in the Covered Period, in October 2007, Walgreens reviewed its existing pool of PSC program members and identified approximately 13,000 PSC members who were beneficiaries of the Medicare and Medicaid programs. Walgreens removed those government beneficiaries from the PSC program at that time precisely because it understood that allowing government beneficiaries to participate in the PSC program was a violation of the AKS. Indeed, when Walgreens removed the 13,000 government beneficiaries from the PSC program in October 2007, it explained in an internal company news release that "the removal was necessary to comply with State/Federal regulations."

55. Walgreens' understanding of the legality of enrolling government beneficiaries in the PSC program did not change after October 2007 or at any point during the remainder of the Covered Period. For example, an internal company document from December 2008 notes that "PSC excludes any patient that is enrolled in a publicly funded health care program due to legal restrictions," including the "[a]nti-kickback statute[]."

56. Similarly, in an email from June 2009, the Walgreens official in charge of the PSC program confirmed to another Walgreens employee that allowing government beneficiaries to enroll in the PSC program would be "a direct violation of [the] anti-kickback or inducement rules."

57. Moreover, in a June 2010 submission to one of its state regulators regarding the PSC program, Walgreens stated:

In constructing the PSC program, Walgreens determined that it would be improper to offer Medicaid and Medicare beneficiaries the discounts and benefits afforded to PSC members since doing so could improperly induce such beneficiaries to obtain their publicly funded goods and services from Walgreens in violation of federal Anti-Inducement law.

58. Throughout the Covered Period, Walgreens was thus well aware that it was a violation of the AKS to allow government beneficiaries to participate in the PSC program.

V. Walgreens Marketed the PSC Program to Government Beneficiaries and Incentivized Its Employees to Enroll Customers in the PSC Program, Regardless of Whether the Customers Were Government Beneficiaries

59. Notwithstanding Walgreens' understanding throughout the Covered Period that allowing government beneficiaries to participate in the PSC program was a violation of the AKS, Walgreens nevertheless routinely marketed the PSC program to government beneficiaries.

60. For example, when a customer who was not a PSC member picked up a prescription at a Walgreens' pharmacy, Walgreens provided the customer with a computer-

generated leaflet that solicited the customer to enroll in the PSC program, including by identifying the amount of money that the customer purportedly would save on the prescription if he or she enrolled in the PSC program and filled the prescription through the PSC program. Walgreens provided these leaflets to all types of customers, including government beneficiaries. During the Covered Period, Walgreens provided many such leaflets to government beneficiaries.

61. During the Covered Period, Walgreens also incentivized its employees to enroll customers in the PSC program, regardless of whether the customers were government beneficiaries. In addition to setting goals for the number of PSC enrollments it expected for individual pharmacy locations and pressuring employees at those locations to meet the goals, Walgreens also offered pharmacy employees monetary bonuses based on the number of unique customers they enrolled in the PSC program. Importantly, in calculating the number of customers that pharmacy employees had enrolled in the PSC program for purposes of determining the amount of bonus money such employees were due, Walgreens did not verify that the enrolled customers were not government beneficiaries.

62. For example, in 2008, Walgreens implemented a program pursuant to which it paid pharmacy employees \$5 for each customer they enrolled in the PSC program on certain, designated PSC enrollment days (referred to internally as “PSC Days”), and \$3 for each customer they enrolled in the PSC program on all other days. In 2009, Walgreens modified the incentive to \$3 for each customer enrolled on PSC Days, and \$1 for each customer enrolled on all other days. In calculating the number of customers that a pharmacy employee enrolled in the PSC program — and thus the amount of money due to be paid to the employee pursuant to this incentive program — Walgreens did not check whether the customers who had been enrolled were government beneficiaries.

63. Walgreens' practice of paying employees for each customer they enrolled in the PSC program led to significant growth in the number of PSC program members. For example, in an email from September 2009, a Walgreens official boasted that the most recent PSC Day resulted in more than 8,000 new enrollments, and he stated that he anticipated the next PSC Day would result in more than 10,000 new enrollments.

64. Predictably, Walgreens' practice of marketing the PSC program to government beneficiaries, as well as the incentives it provided to its employees to enroll customers in the PSC program (regardless of whether the customers were government beneficiaries), resulted in the enrollment of a substantial number of government beneficiaries in the PSC program during the Covered Period.

VI. Walgreens Knowingly Enrolled Hundreds of Thousands of Government Beneficiaries in the PSC Program

65. Throughout the Covered Period, Walgreens maintained data reflecting each prescription filled by each of its customers. This data reflects that, throughout the Covered Period, Walgreens enrolled hundreds of thousands of government beneficiaries in the PSC program. For these government beneficiaries, Walgreens' data shows that the beneficiaries filled prescriptions using government healthcare programs during the same period when they were enrolled in and also filling prescriptions using the PSC program.

66. The data further indicates that many of the government beneficiaries who were enrolled in the PSC program alternated between using the PSC program and their government healthcare program to fill their prescriptions, depending on which program they believed offered them a more favorable price. For example:

- Customer A, a Medicare beneficiary from Florida, filled a prescription using Medicare on April 29, 2008, a prescription using the PSC program on May 21, 2008, and another prescription using Medicare on June 13, 2008.

- Customer B, a Medicaid beneficiary from California, filled a prescription using Medicaid on May 18, 2008, two prescriptions using the PSC program on July 13 and July 22, 2008, and another prescription using Medicaid on September 25, 2008.
- Customer C, a Medicare beneficiary from California, filled a prescription using the PSC program on November 12, 2008, two prescriptions using Medicare on November 18 and December 2, 2008, and another prescription using the PSC program on December 11, 2008.
- Customer D, a TRICARE beneficiary from Illinois, filled a prescription using TRICARE on September 4, 2007, a prescription using the PSC program on September 29, 2007, three additional prescriptions using TRICARE on October 2 and 16, 2007, and another prescription using the PSC program on October 30, 2007.
- Customer E, a Medicare beneficiary from Illinois, filled a prescription using Medicare on August 19, 2008, a prescription using the PSC program on September 4, 2008, another prescription using Medicare on September 19, 2008, and another prescription using the PSC program on October 4, 2008.
- Customer F, a Medicaid beneficiary from California, filled a prescription using the PSC program on November 28, 2008, a prescription using Medicaid on February 7, 2009, and another prescription using the PSC program on May 29, 2009.
- Customer G, a Medicare beneficiary from California, filled a prescription using Medicare on January 18, 2009, a prescription using the PSC program on February 18, 2009, and another prescription using Medicare on June 9, 2009.
- Customer H, a TRICARE beneficiary from Illinois, filled a prescription using TRICARE on April 3, 2009, a prescription using the PSC program on May 22, 2009, and another prescription using TRICARE on June 9, 2009.
- Customer I, a Medicaid beneficiary from New York, filled a prescription using Medicaid on September 29, 2009, a prescription using the PSC program on November 28, 2009, and another prescription using Medicaid on December 19, 2009.
- Customer J, a Medicare beneficiary from Florida, filled a prescription using the PSC program on July 27, 2009, a prescription using Medicare on September 1, 2009, another prescription using the PSC program on September 29, 2009, and another prescription using Medicare on October 2, 2009.

- Customer K, a Medicare beneficiary from Florida, filled a prescription using the PSC program on May 6, 2009, a prescription using Medicare on May 18, 2009, another prescription using the PSC program on July 22, 2009, and another prescription using Medicare on August 19, 2009.

67. Throughout the Covered Period, Walgreens had actual knowledge or deliberately or recklessly disregarded that significant numbers of government beneficiaries were enrolling and participating in the PSC program. As an initial matter, a review of the internal data referenced above — to which Walgreens had ready access — would have revealed that hundreds of thousands of government beneficiaries were enrolled and participating in the PSC program.

68. Moreover, during the Covered Period, employees at Walgreens' pharmacies nationwide made notations in Walgreens' internal customer database reflecting that tens of thousands of government beneficiaries were purchasing drugs using the PSC program. The employees made these notations in the address fields for these customers. For example:

- Customer L, a Medicare beneficiary from Florida, had Medicare Part D listed as his primary insurance in the customer database, but his address field included the note “*WCARD METO/SIMVA”.²
- Customer M, a Medicare beneficiary from Illinois, had Medicare Part D listed as her primary insurance in the customer database, but her address field included the note “wcard on digoxin”.
- Customer N, a Medicaid beneficiary from Texas, had Medicaid listed as his primary insurance in the customer database, but his address field included the note “*testosterone-wcard*”.
- Customer O, a TRICARE beneficiary from Florida, had TRICARE listed as her primary insurance in the customer database, but her address field included the note “+BRAND COUMADIN+WCARD+”.
- Customer P, a Medicare beneficiary from Florida, had Medicare Part D listed as his primary insurance in the customer database, but his address field included the note “(wcard if cheaper)”.

² As set forth above, Walgreens referred to the PSC program membership card as the “WCard.”

- Customer Q, a Medicare beneficiary from Ohio, had Medicare Part D listed as her primary insurance in the customer database, but her address field included the note “wcard on some things”.
- Customer R, a Medicaid beneficiary from New York, had Medicaid listed as her primary insurance in the customer database, but her address field included the note “*pt has wcard*”.
- Customer S, a Medicare beneficiary from Texas, had Medicare Part D listed as her primary insurance in the customer database, but her address field included the note “**some on wcard”.
- Customer T, another Medicare beneficiary from Texas, had Medicare Part D listed as her primary insurance in the customer database, but her address field included the note “**wcard for hyoscyamine*”.
- Customer U, a Medicaid beneficiary from Illinois, had Medicaid listed as his primary insurance in the customer database, but his address field included the note “*pt has wcard*check both”.

69. A cursory review by Walgreens of its above-referenced internal customer database would have revealed evidence of significant participation by government beneficiaries in the PSC program.

70. Moreover, after removing the above-referenced approximately 13,000 government beneficiaries from the PSC program in October 2007 — precisely because these individuals were government beneficiaries — Walgreens allowed many of the very same government beneficiaries to re-enroll in the program.

71. In addition, as set forth above, after October 2007 Walgreens actively marketed the PSC program to government beneficiaries through the above-referenced leaflets, and it incentivized its employees to enroll customers in the program, without regard to whether the customers were government beneficiaries.

72. Finally, after October 2007, Walgreens ignored additional evidence of significant government beneficiary participation in the PSC program. For example, in August 2010,

Walgreens conducted an analysis of PSC program members in one particular state, and that analysis revealed that about half of the PSC program members in that state in 2009 and 2010 were government beneficiaries. A similar analysis of other states would have revealed similar information: that significant numbers of government beneficiaries in those states were also enrolling in the PSC program.

73. At best, Walgreens turned a blind eye to its enrollment of substantial numbers of government beneficiaries in the PSC program during the Covered Period. This served Walgreens' own financial self-interest, as Walgreens feared that if it did not make the PSC program benefits available to its customers, many of them would take their pharmacy business to one of its competitors. Had government beneficiaries opted to fill their prescriptions at one of Walgreens' competitors, Walgreens would have lost a substantial amount of money that it obtained through (1) filling the government beneficiaries' prescriptions, and thereafter (2) seeking reimbursement for many of those prescriptions from the beneficiaries' government healthcare programs.

VII. Walgreens' Compliance Program Was Inadequate to Prevent Government Beneficiaries from Enrolling and Participating in the PSC Program

74. During the Covered Period, Walgreens did not have sufficient controls in place to prevent (1) government beneficiaries from participating in the PSC program, and thus (2) the PSC program from serving as a vehicle to pay kickbacks to government beneficiaries through discounts on prescription drugs and other benefits.

75. Indeed, during the Covered Period, the only mechanism that Walgreens put in place to protect against government beneficiaries participating in the PSC program was to have government beneficiaries — a set of customers to whom it marketed the program and who it told would benefit from enrolling in the program — make a representation at the time of enrollment

that they were not, in fact, government beneficiaries. This was patently insufficient, particularly given that Walgreens (1) recognized that the program was attractive to government beneficiaries and (2) was actively marketing the program to government beneficiaries. Indeed, as of October 2007, Walgreens knew that no fewer than 13,000 government beneficiaries had successfully enrolled in the PSC program, and it thereafter provided the above-described leaflets to government beneficiaries showing them how much money they could save on particular prescriptions if they purchased them through the PSC program.

76. Although Walgreens could have taken additional steps to police against government beneficiaries enrolling in the PSC program, it did not do so. For example, it did not set its internal computer system to (1) block individuals who had a government healthcare program on file in its system from enrolling in the PSC program, or (2) flag such individuals as government beneficiaries if and when they sought to enroll in the PSC program. Walgreens failure to take these or other additional steps was particularly problematic after October 2007.

77. Nor did Walgreens have effective procedures in place to audit the PSC program for purposes of policing against government beneficiaries participating in the program. As set forth above, Walgreens possessed data that if reviewed with any reasonable degree of diligence, would have revealed that hundreds of thousands of government beneficiaries were participating in the PSC program. Indeed, the August 2010 analysis referenced above — which looked only at the PSC program members in one particular state in 2009 and 2010 — revealed that about half of them were government beneficiaries.

VIII. Walgreens Submitted and Caused to Be Submitted Many False Claims that Were Paid for by Federal Healthcare Programs

78. Through the PSC program, Walgreens knowingly provided kickbacks to hundreds of thousands of government beneficiaries — in the form of discounts and rebates on prescription

medications and other store items — to induce the government beneficiaries to fill all of their prescriptions at its pharmacies, including those that were paid for in full or in part by government healthcare programs.

79. Many of the government beneficiaries who received the above-referenced kickbacks, in fact, filled prescriptions at Walgreens' pharmacies that were paid for in full or in part by Medicare, Medicaid or TRICARE. As discussed above, many of the government beneficiaries who were enrolled in the PSC program alternated between using the PSC program and their government healthcare program to fill prescriptions. In connection with those prescriptions that such beneficiaries filled using their government healthcare programs, Walgreens submitted claims for reimbursement to those government healthcare programs, and it ultimately received millions of dollars in reimbursements from those programs.

80. Walgreens is liable to the United States for damages based on the payment of the above-referenced claims for reimbursement, because the claims were tainted by Walgreens' unlawful kickback activity.

81. Compliance with the AKS is a precondition of payment by the above-referenced government healthcare programs (or their designees) by virtue of federal and state statutes, regulations, provider agreements, and contracts.

82. As set forth above, Walgreens and other participants in the Medicare, Medicaid and TRICARE claims processes submitted certifications and attestations in which they certified compliance with the AKS. Kickbacks that were paid to government beneficiaries as alleged herein rendered those certifications and attestations false. Those false certifications and attestations were material to the decisions by the government healthcare programs (or their designees) to pay the false claims for reimbursement that Walgreens submitted, or caused to be

submitted, for prescriptions that were tainted by Walgreens' kickback activity as described herein.

83. Claims for reimbursement for prescriptions tainted by the kickbacks expressly and impliedly misrepresented compliance with a material condition of payment, *i.e.*, compliance with the AKS. Such claims that were tainted by a violation of the AKS constitute false or fraudulent claims under the FCA. 42 U.S.C. § 1320a-7b(g).

84. Walgreens knew that the remuneration it provided to government beneficiaries in connection with the PSC program was an inducement to those beneficiaries to self-refer all of their prescription medications to Walgreens' pharmacies. It was reasonably foreseeable that such government beneficiaries would purchase some of their prescription medications using their government healthcare programs, and that claims for those prescriptions would be submitted to and paid for by those government healthcare programs. And that is precisely what occurred, in violation of the AKS and FCA.

FIRST COUNT

Violations of the False Claims Act: Presenting False Claims for Payment (31 U.S.C. § 3729(a)(1) (2006), and, as amended, 31 U.S.C. § 3729(a)(1)(A))

85. The United States incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

86. The United States seeks relief against defendant under 31 U.S.C. § 3729(a)(1) (2006) and, as amended, 31 U.S.C. § 3729(a)(1)(A).

87. As set forth above, Walgreens provided kickbacks to government beneficiaries through the PSC program, which had the effect of inducing government beneficiaries to fill prescriptions at Walgreens' pharmacies using their government healthcare programs, in violation of the AKS, 42 U.S.C. § 1320a-7b(b)(2). In connection with these kickback-tainted

prescriptions, Walgreens made false and fraudulent claims for reimbursement to government healthcare programs. As a result, Walgreens knowingly presented or caused to be presented false or fraudulent claims for payment or approval in violation of 31 U.S.C. § 3729(a)(1)(2006), and, as amended, 31 U.S.C. § 3729(a)(1)(A).

88. By reason of the false or fraudulent claims, the United States has sustained damages in a substantial amount to be determined at trial, and is entitled to treble damages plus a civil penalty for each violation.

SECOND COUNT

Violations of the False Claims Act: Use of False Statements (31 U.S.C. § 3729(a)(2) (2006), and, as amended, 31 U.S.C. § 3729(a)(1)(B))

89. The United States incorporates by reference each of the preceding paragraphs as if fully set forth herein.

90. The United States seeks relief against defendant under the False Claims Act, 31 U.S.C. § 3729(a)(2)(2006), and, as amended, 31 U.S.C. § 3729(a)(1)(B).

91. As set forth above, Walgreens provided kickbacks to government beneficiaries through the PSC program, which had the effect of inducing government beneficiaries to fill prescriptions at Walgreens' pharmacies using their government healthcare programs, in violation of the AKS, 42 U.S.C. § 1320a-7b(b)(2). In connection with these kickback-tainted prescriptions, Walgreens knowingly made or used, or caused others (such as PBMs and Part D sponsors) to make or use, false records or statements that were material to false or fraudulent claims for payment submitted to government healthcare programs.

92. By reason of these false records or statements, the United States has sustained damages in a substantial amount to be determined at trial, and is entitled to treble damages plus a civil penalty for each violation.

THIRD COUNT

Unjust Enrichment

93. The United States incorporates by reference each of the preceding paragraphs as if fully set forth herein.

94. The United States paid claims submitted to federal healthcare programs based on false statements submitted to government healthcare programs (or their designees) as a result of Walgreens' above-referenced violations of the AKS, 42 U.S.C. § 1320a-7b. The circumstances of Walgreens' receipt of payments in connection with prescriptions that were tainted by its kickback activity are such that, in equity and good conscience, Walgreens should not retain those payments, the amount of which is to be determined at trial.

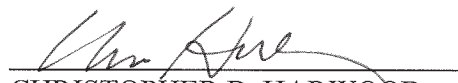
WHEREFORE, the United States respectfully requests judgment against Walgreens as follows:

- a. On Counts One and Two (FCA), a judgment against Walgreens for treble damages and civil penalties to the maximum amount allowed by law;
- b. On Count Three (common law), a judgment for damages to the extent allowed by law.

Dated: January 18, 2017
New York, New York

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